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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,814	04/19/2005	Masaomi Iyo	268519US0PCT	4204

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EXAMINER
HAYES, ROBERT CLINTON

ART UNIT	PAPER NUMBER
1649	

NOTIFICATION DATE	DELIVERY MODE
01/06/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/528,814	IYO ET AL.	
	Examiner	Art Unit	
	Robert C. Hayes, Ph.D.	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-10 and 13-20* is/are pending in the application.

4a) Of the above claim(s) *4-6 and 13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-10 and 14-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *4-10 and 13-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed on 9/30/08 has been entered.

2. The rejection of claims 7-9 under 35 U.S.C. 112, second paragraph, as being indefinite and incomplete is withdrawn due to the amendment of base claim 7. It is suggested that claim 7, line 5, be amended to "the BDNF level in a normal control subject…", in order to reflect more conventional claim language.

3. The rejection of claims 7-10 under 35 U.S.C. 103(a) as being unpatentable over Barde et al (U.S. Patent 5,180,820), in view of Kernie et al (2000; IDS Ref #AW) is withdrawn due to the amendment of the claims to recite a "decrease concentration/lower level of BDNF in blood/ serum" as indicative of anorexia nervosa and/or bulimia nervosa. Applicant correctly argues that "Kernie teaches away from an association between low levels of BDNF… and anorexia nervosa and bulimia nervosa", because Kernie teaches lower levels of BDNF are alternatively indicative of obesity.

4. Applicant's arguments filed 9/30/08 have been fully considered but they are not deemed to be persuasive.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 7-10 & new claims 14-20 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons made of record in Paper No: 20080325, and as follows. This remains a written description rejection.

Applicant argues on pages 5-6 of the response that "[t]his rejection is moot in view of the amendments clarifying the claim language…". In contrast to Applicant's assertion, although amendment of the claims to limit the eating disorders to "anorexia nervosa and bulimia nervosa" "in a human subject" correctly addresses this part of the written description rejection, the recitation of "brain-derived neurotrophic factor **or BDNF**" appears to still attempt to claim a generic BDNF molecule. In contrast, human brain-derived neurotrophic factor is abbreviated as human BDNF, and should not be used to broaden the scope of the claim.

It is suggested that amending claims 7, 8, 9, 10 & 14 to "brain-derived neurotrophic factor (BDNF)" should obviate this part of this rejection.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described

in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

No proper antecedent basis or conception in context with that described within the specification at the time of filing the instant application is apparent on page 19 (Example 2) for the recitation of "*detecting BDNF levels in blood or serum* [of a *human* subject] before *and after therapeutic treatment of anorexia nervosa or bulimia nervosa*". In contrast, administrating BDNF to a heterozygous male mouse (BDNF +/-) and observing decreased food intake is not equivalent to "detecting BDNF levels" before and after treatment, especially in two related, but different, *human* conditions; thereby, constituting new matter.

8. Claims 10 & 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Although putative "therapeutic agents" are described on pages 6, 9-10, 19 and Table 1 in the specification for treating anorexia nervosa and bulimia nervosa, page 19 of the specification (i.e., Example 2) alternatively discloses that administration of BDNF resulted in a "decrease" in "food intake per day", which would reasonably exasperate anorexia nervosa, not treat this condition; in contrast to Applicants' conclusion on page 19 of the specification. Accordingly, not a single reasonably successful "therapy" is therefore disclosed within the instant specification for treating anorexia nervosa and bulimia nervosa. This is consistent with the state of the art, as

illustrated by Kernie (2000; IDS Ref #AW), who alternatively teaches that lower levels of BDNF are indicative of obesity (i.e., NOT anorexia nervosa and bulimia nervosa). Thus, the exact opposite from that claimed using BDNF would be expected to occur; thereby, requiring undue experimentation for the skilled artisan to know how to make and use the invention with any expectation of success for any additional "therapeutic treatment" step, or any method "for detecting a therapeutic agent" recited in these claims (i.e., as it relates to treating anorexia nervosa and bulimia nervosa).

9. Claim 10 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite and incomplete for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As previously made of record, the current method remains incomplete for not reciting how and when one knows they have completed the claimed method, as recited in the preamble (i.e., detecting a [putative] therapeutic agent). For example, no relationship to any corresponding increase or decrease in BDNF levels is recited. In other words, the claim still merely recites measuring for some unknown "concentration", which has no nexus to the preamble.

10. Claims 17-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite and incomplete for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

No further "test" step for anorexia nervosa or bulimia nervosa is recited for the newly submitted method, in which it is confusing what this test entails, because base claim 14 already

defines "detecting… anorexia nervosa and bulimia nervosa" as a result of detecting "lower level[s] of BDNF" (i.e., a test), which therefore appears either contradictory, or redundant.

11. Note that *In re Ochiai* , in the case of an *elected product claim*, when a product claim is found allowable, withdrawn process claims which depend from or otherwise include all the limitations of an allowable product claim will be rejoined. In contrast, the instant elected invention of Group II was directed toward method/process claims; not product claims.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Stucker, can be reached on (571) 272-0911. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Robert C. Hayes/
Primary Examiner, Art Unit 1649
December 30, 2008